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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,590	10/27/2000	Judith Fitzpatrick	018792/0177	3507

22428 7590 09/15/2005

FOLEY AND LARDNER
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WASHINGTON, DC 20007

EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/697,590	FITZPATRICK ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Turner, Art Unit 1649.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-16-05 has been entered.

3. The amendment filed 4-4-05 has been entered into the record and has been fully considered.

4. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

5. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn.

6. Claims 1-5, 7-22, 24-53, 56 and 57 are canceled. Claims 55 and 58 are pending and are under Examination.

Rejections Necessitated by Amendment

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 55 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending Application No. 10/146,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is similarly drawn to isolated neural thread protein (NTP) peptides corresponding to species of HARL sequences, with additional NTP residues and which are deemed to inherently bind to themselves based upon the presence of the NTP sequence, known and evidenced to bind to itself as disclosed in the art, see for example, specification and de la Monte of record below. While the '130 claims are drawn to the peptides provided in a composition of matter claim, patenting of the claim may render obvious instant peptide comprising the same segments of neural thread protein as instantly claimed. The delineated species fall squarely within the boundaries of instant claims and would therefore anticipate the genus of peptides now recited.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants request in the response of 4-4-05 that the double patenting rejection be held in abeyance until such time that a notice of allowance is issued. No comments as to the correctness of the rejection have been noted.

Applicants arguments filed 4-4-05 have been fully considered but are not persuasive for withdrawal of the rejection. No comments as to the correctness of the rejection are noted. Therefore rejection is maintained as set forth in MPEP 804, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Claim Rejections - 35 USC § 112

9. Claims 55 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 55 and 58 are newly presented as in the amendment of 10-4-04. Support for the new recitations is as noted in the figure spanning pp. 20-23 of the 10-4-04 response. These citations have been fully considered. However, support for the recitations is not garnered due to the inexactness of the recitations as noted. In

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particular, Applicant's claims recite elements with respect to an "HARL" core sequence whereas in contrast the specification only denotes longer core sequences as in for example elements a-d at p. 8-9 spanning which recite for example "THARLIL", "HHARLCL", "MFARLIL", and "HHARLIF". Also noted at p. 9 are cores of "HARLML" as directed at p. 9, line 5. While the specification at p. 9, lines 15-16 does recite "Preferably, the Harlil peptide having additional amino acid residues does not exceed 25 total amino acids in length", the cores are not of "HARL" as now recited in the claims. Moreover, the claims combine particular elements, for example the preamble of "does not exceed 25 amino acids in length" is combined with elements a) and b) of the claims directed to a core of "HARL" and "additional amino acids before and after the amino acid sequence HARL of said peptide correspond to those amino acids found in a Neural Thread Protein (NTP) sequence" and as in claims 56-58 element c) said peptide binds to NTP. Support is not garnered in particular for this combination of elements to define a new sub-genus not supported by the specification as originally filed. Accordingly, the full recitations of the claims constitute new matter.

Applicants argue via reference to MPEP 2163(I)(B) that the written description requirement is not an *in haec verba* requirement and that the various 6-7 mer sequences all comprise the HARL core motif. Applicants further argue that original claim 1(b), 6, 23(b) and 25(b) provides an as-filed *ipsis verbis* standard with further reference to *In re Benno*. Regarding the combination of the elements, Applicants refer to pps. 1-7, 9-11, 13-17, 21-23 and original claims 6 and 28 for support of the combination of elements.

Applicants arguments filed 4-4-05 have been fully considered but are not persuasive. None of the noted citations or original claims support (expressly, implicitly or inherently) the instant sub-generic claims as recited. The specification particularly at pp. 5-9 is the most supportive of similar language, but even here the disclosure does not arrive at the newly-described and delineated set of characteristics that define a sub-generic family related by the recited 4 (or more) requirements of 'not exceeding 25 amino acids in length', 'contain(ing)... HARL', 'where the additional amino acids before and after correspond to NTP', and that 'bind NTP'. As in Applicants reference to MPEP 2163(I)(B) "New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Accordingly this citation supports the Examiner's rejection as the conglomeration of related constraints that define the claims differ from the terms in the originally filed specification and claims such that the claims now define a new and unsupported sub-genus or family thereby constituting a new matter issue and a lack of written description support.

With respect to Applicant's referral to *In re Benno*, the MPEP here notes "The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § 2163.06 through § 2163.07 for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed." This reference is not on point where it is the claims that are unsupported by the specification and claims as originally filed. No amendments other than sequence identifier insertions are believed to have been made at the relevant portions of the specification.

For these reasons, rejection is maintained.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 55 and 58 are rejected under 35 U.S.C. 102(e) and (b) as being anticipated by Kubota et al., US 5,834,287 filed Feb. 26, 1996 and issued Nov. 10, 1998, page 1 and columns 37-42, SEQ ID NO's:5-10 as further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Kubota et al., teach peptides of SEQ ID NO's:5-10. The length of the peptides are from 17-21 amino acids in length. In particular, SEQ ID NO:8 is comprised of the sequence "LDWAEASAGD**HARL**LE" comprising the HARL motif and additional amino acids before and after the amino acid sequence HARL of said peptide correspond to those amino acids found in a Neural thread protein sequence. In particular, the full length neural thread protein is noted as evidenced in de la Monte US 5,830,670 below. The amino acids "LDWAWASAGD" prior and "LE" after are additional amino acids that

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are found in a neural thread protein sequence. The claim does not require that the amino acids bear any particular homology to any particular portion of the neural thread protein sequence but merely require that they may be found in the full length sequence. In particular, the sequence bears 100% similarity where bolded (HARL) and accordingly is a homolog of HARL in that it comprises the HARL motif further bears additional sequences of the neural thread protein. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

Applicants argue in the 4-4-05 response that the Kubota sequence does not relate to NTP and therefore it does not teach or suggest that the sequence is capable of binding NTP, thereby not meeting each and every limitation of the claims.

Applicants' arguments have been fully considered but are not persuasive. A peptide cannot be separated from its inherent properties. As previously noted the reference meets the structural limitations of the claims. The reference is silent as to whether or not the peptide possesses the property of binding NTP. Yet consistent with Applicants' disclosure the HARL motif is considered to be a determining factor in this binding characteristic and therefore the property is deemed to be inherent absent

factual evidence to the contrary. The PTO has insufficient resources to test the Kubota peptide for its properties. Applicant's arguments cannot substitute for evidence. As the structural requirements of the claims are met and the peptide provides the HARL motif that directs binding to NTP, this property is an inherent characteristic absent factual evidence to the contrary. Therefore, rejection is maintained.

12. Claims 58 is rejected under 35 U.S.C. 102(a) as being anticipated by Rosen et al., WO 00/55199 published 21 September, 2000, page 1 and 74, SEQ ID NO:123 as further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Rosen et al., teach peptide of SEQ ID NO:123. The length of the peptide is 17 amino acids comprised of the sequence "**ASASQSAGITGVSHHAR**" bearing 65.4% identity to SEQ ID NO:2 residues 270-295 "ISGPCDLP**ASASQSAGITGVSHHARL**". In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog or mimetic of HARL in that it comprises the HARL motif with only the L is deleted (a homolog) and further bears additional sequences of the neural thread protein. In addition, the full length neural thread protein is noted as evidenced in de la Monte US 5,830,670 below. The amino acids prior are additional amino acids that are found in a neural thread protein sequence. In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the

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contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

Applicants argue that the Rosen peptide does not contain the full HARL sequence as required of claim 58 and accordingly does not anticipate.

Applicants arguments have been fully considered but are not persuasive. Claim 58 is directed to a mimetic. The characteristics to which applicant refers are those of the peptide and not the mimetic. The mimetic is not structurally or functionally constrained and therefore the Rosen peptide suitably anticipates. Therefore rejection is maintained.

13. Claims 58 is rejected under 35 U.S.C. 102(e) as being anticipated by Lo et al., US 6,610,506 filed Nov. 29, 1996, page 1 and columns 121-122, SEQ IDNO:53 as further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Lo et al., teach peptide of SEQ ID NO:53. The length of the peptide is 17 amino acids comprised of the sequence "Y**A**IRGV**D**L**NRV**S**L**LVD" bearing 21.5% identity to SEQ ID NO:2 residues91-113 "H**A**R**L**CLAN**F**CG**R**N**R**V**S**L**M**C**P**S**W**S" . In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL in that is comprises the HARL motif with the H deleted and the RL substituted attached to additional sequences of the neural thread protein (NRVSL) as noted above. The claim

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does not require that the amino acids bear any particular homology to any particular portion of the neural thread protein sequence but merely require that they may be found in the full length sequence. In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL attached to additional amino acids found in the neural thread protein. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 directed to homologs and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

Applicants argue in the 4-4-05 response that the Lo peptide does not contain the full HARL sequence as required of claim 58 and accordingly does not anticipate.

Applicants arguments have been fully considered but are not persuasive. Claim 58 is directed to a mimetic. The characteristics to which applicant refers are those of the peptide and not the mimetic. The mimetic is not structurally or functionally constrained and therefore the Lo peptide suitably anticipates. Therefore rejection is maintained.

14. Claims 58 is rejected under 35 U.S.C. 102(b) as being anticipated by de la Monte et al., US Patent 5,830,670 filed 5-30-1995 and issued 11-3-1998.

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Claim 58 is drawn to "An isolated mimetic". The limitations of "said peptide" are not limitations of the mimetic. de la Monte et al., teach isolated neural thread protein comprising or having the HARL motif, see in particular SEQ ID NO:120. The peptide is flanked by portions of the neural thread protein sequence. Moreover, Monte notes that neural thread protein aggregates and binds to itself, see in particular examples 2-3, 12 and 14-16, particularly in Alzheimer's and Down's syndrome plaques. Thus, as the mimetic is not delimited via any structural or functional limitations, the full length peptide would meet the claim limitations of a mimetic as the full length peptide approximates the peptide characteristics even though it is longer in length. Thus the reference teachings anticipate the claimed invention.

Applicants argue in the 4-4-05 response that the de la Monte peptides are not peptides that do not exceed 25 amino acids in length as required of claim 58 and accordingly does not anticipate.

Applicants arguments have been fully considered but are not persuasive. Claim 58 is directed to a mimetic. The characteristics to which applicant refers are those of the peptide and not the mimetic. The mimetic is not structurally or functionally constrained and therefore the Rosen peptide suitably anticipates. Therefore rejection is maintained.

Status of Claims

15. No claims are allowed.

Conclusion

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16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at (571) 272-0867.

Sharon L. Turner, Ph.D.
July 24, 2005


SHARON TURNER, Ph.D.
PRIMARY EXAMINER
7-24-05